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#1636

**CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: U.S. Patent & Trademark Office, P.O. Box 2327, Arlington, VA 22202

Marcia Rossell  
Type or print name

*Marcia Rossell*  
Signature

April 7, 2003  
Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF

Confirmation No. 4496

CHENG, ET AL.

Art Unit: 1636

APPLICATION NO: 10/081,969

Examiner: Marvich, Maria

FILED: FEBRUARY 22, 2002

Atty. Docket: 4-31704A

FOR: NOVEL ONCOLYTIC ADENOVIRAL VECTORS

U.S. Patent & Trademark Office  
P.O. Box 2327  
Arlington, Virginia 22202

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**TRANSMITTAL LETTER**

Sir:

Enclosed please find the following:

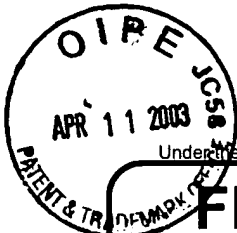
- a. Information Disclosure Statement (1 page);
- b. PTO Form 1449 (20 pages) with cited references;
- c. Fee Letter for Information Disclosure Statement;
- d. Fee Transmittal Sheet; and
- e. Return postcard.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Bldg. 430  
East Hanover, NJ 07936-1080  
(301) 258-4832

*Douglas Golightly*  
\_\_\_\_\_  
Douglas Golightly  
Patent Agent  
Reg. No. 51,244

Date: April 7, 2003



# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180

## Complete if Known

Application Number	10/081,969
Filing Date	February 22, 2002
First Named Inventor	Cheng
Examiner Name	Marvich, Maria
Art Unit	1636
Attorney Docket No.	4-31704A

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 19-0134  
Deposit Account Name: Novartis Corporation

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments  
☐ Charge any additional fee(s) during the pendency of this application  
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1001 750	2001 375	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 520	2003 260	Plant filing fee	
1004 750	2004 375	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$ )

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims:  -20\*\* =  X  =   
Independent Claims:  -3\*\* =  X  =   
Multiple Dependent:  =

Large Entity	Small Entity	Fee Description
Fee Code (\$)	Fee Code (\$)	
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ )

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 410	2252 205	Extension for reply within second month	
1253 930	2253 465	Extension for reply within third month	
1254 1,450	2254 725	Extension for reply within fourth month	
1255 1,970	2255 985	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,300	2453 650	Petition to revive - unintentional	
1501 1,300	2501 650	Utility issue fee (or reissue)	
1502 470	2502 235	Design issue fee	
1503 630	2503 315	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 750	2809 375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 750	2810 375	For each additional invention to be examined (37 CFR 1.129(b))	
1801 750	2801 375	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ ) 180

## SUBMITTED BY

(Complete if applicable)

Name (Print/Type)	Douglas Golightly	Registration No. (Attorney/Agent)	51,244	Telephone	301-258-4832
Signature		Date	April 7, 2003		

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

CHENG, ET AL.

APPLICATION NO: 10/081,969

FILED: FEBRUARY 22, 2002

FOR: NOVEL ONCOLYTIC ADENOVIRAL VECTORS

Confirmation No. 4496

Art Unit: 1636

Examiner: Marvich, Maria

Atty. Docket: 4-31704A

U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

INFORMATION DISCLOSURE STATEMENT

RECEIVED  
APR 14 2003  
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Sir:

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. §1.97(c).  
A letter for payment of fee set forth in 37 C.F.R. §1.17(p) is enclosed.

In accordance with 37 C.F.R. §1.56, applicant wishes to call the Examiner's attention to the references cited on the attached form(s) PTO-1449. Copies of these references are enclosed herewith.

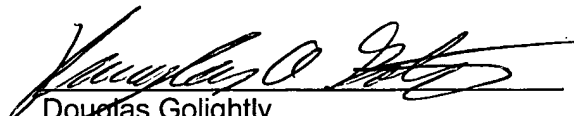
The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

04/11/2003 HMEKONEN 00000054 190134 10081969

01 FC:1806 180.00 CH

Novartis  
Corporate Intellectual Property  
One Health Plaza, Bldg. 430  
East Hanover, NJ 07936-1080  
(301) 258-4832

  
Douglas Golightly  
Patent Agent  
Reg. No. 51,244

Date: April 7, 2003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

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APR 14 2003

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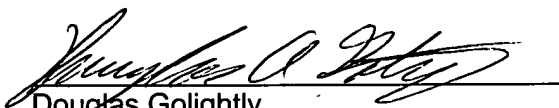
FEE LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Please charge Deposit Account No. 19-0134 in the name of Novartis Corporation in the amount of \$180 for payment of the fee pursuant to 37 CFR §1.17(p) for the submission of an Information Disclosure Statement under 37 CFR §1.97(c). The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Bldg. 430  
East Hanover, NJ 07936-1080  
(301) 258-4832

  
Douglas Golightly  
Patent Agent  
Reg. No. 51,244

Date: April 7, 2003

FORM PTO-1449  
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.

4-31704A

APPLICATION NO.

10/081,969

APPLICANT

Ennist, et al.

FILING DATE

FEBRUARY 22, 2002

Group



(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	10/081,961	2/22/02	Gorziglia, et al.			
	AB	2001/0006633A1	7/5/01	Kirn, D.			
	AC	5,672,344	9/30/97	Kelley, et al.			
	AD	5,677,178	10/14/97	McCormick, F.			
	AE	5,698,443	12/16/97	Henderson, et al.			
	AF	5,707,618	1/13/98	Armentano, et al.			
	AG	5,830,686	11/3/98	Henderon, D.			
	AH	5,837,511	11/17/98	Falck-Pederson, et al.			
	AI	5,871,726	2/16/99	Henderson, et al.			
	AJ	5,994,128	11/30/99	Fallaux, et al.			
	AK	5,998,205	12/7/99	Hellenbeck, et al.			
	AL	6,057,299	5/2/00	Henderson, D.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES NO	
	AM	WO 00/03029	1/20/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 00/15820	3/23/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AO	WO 00/22124	4/20/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 00/29599	5/25/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 00/31286	6/2/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Adams, et al., "Transcriptional Control by E2F," <i>Seminars in Cancer Biology</i> , 6:99-108 (1995)
	AS	Albert, et al., "Dendritic Cells Acquire Antigen From Apoptotic Cells and Induce Class I-restricted CTLs," <i>Nature</i> , 392:86-89 (March 1998)
	AT	Aleman, et al., "Replicative Adenoviruses for Cancer Therapy," <i>Nature Biotechnology</i> , 18:723-727 (July 2000)

EXAMINER

DATE CONSIDERED

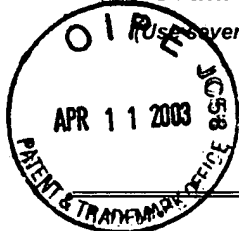
\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449  
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
4-31704A  
APPLICATION NO.  
10/081,969  
APPLICANT  
Ennist, et al.  
FILING DATE  
FEBRUARY 22, 2002

Group

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	6,136,792	10/24/00	Henderson, D.			
	AB	6,197,293 B1	3/6/01	Henderson, et al.			
	AC	6,254,862 B1	7/3/01	Little, et al.			
	AD	6,271,207 B1	8/7/01	Cristiano, et al.			
	AE	6,297,219 B1	10/2/01	Nabel, et al.			
	AF	6,432,700 B1	8/13/02	Henderson, et al.			
	AG	6,436,394 B1	8/20/02	Henderson, et al.			
	AH	6,495,130 B1	12/17/02	Henderson, et al.			
	AI						
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## FOREIGN PATENT DOCUMENTS

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	AN	WO 00/46355 ✓	8/10/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
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	AP	WO 00/56909 ✓	9/28/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 00/67576 -	11/16/00	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	✓ AR	Altmann, et al., "Epothilones and Related Structures -- a New Class of Microtubule Inhibitors with Potent In Vivo Antitumor Activity," <i>Biochemica et Biophysica Acta</i> , 1470:M79-M91 (2000)
	AS	Angelichio, et al., "Comparison of Several Promoters and Polyadenylation Signals for Use in Heterologous Gene Expression in Cultured Drosophila Cells," <i>Nucleic Acids Research</i> , 19(18):5037-5043 (1991)
	AT	Armitage, J., "Emerging Applications of Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor," <i>Blood</i> , 92(12):4491-4508 (December 15, 1998)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

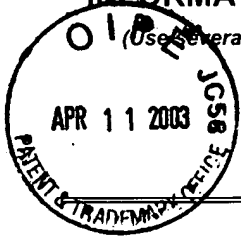
FORM PTO-1449  
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE CITATION

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Group



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	AA						
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## FOREIGN PATENT DOCUMENTS

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	AQ	WO 01/23004 ✓	4/5/01	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	✓	Armstrong, et al., "Antitumor Effects of Granulocyte-Macrophage Colony-Stimulating Factor Production by Melanoma Cells," <i>Cancer Research</i> , 56:2191-2198 (May 1, 1996)
	AS	✓	Axelrod, et al., "A Novel Oncolytic Adenovirus Encoding an IL-6/sIL-6R Fusion Protein," Abstract No. P6, presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002
	AT	✓	Babiss, et al., "Cellular Promoters Incorporated into the Adenovirus Genome: Effects of Viral Regulatory Elements on Transcription Rates and Cell Specificity of Albumin and $\beta$ -Globin Promoters," <i>Molecular and Cellular Biology</i> , 6(11):3798-3806 (November 1986)

EXAMINER

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Ennist, et al.

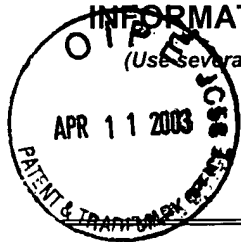
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	AM	WO 01/36650 ✓	5/25/01	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 01/72341	10/4/01	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AO	WO 01/73093	10/4/01	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 02/068627	9/6/02	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 94/18992	9/1/94	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Benedict, et al., "Three Adenovirus E3 Proteins Cooperate to Evade Apoptosis by Tumor Necrosis Factor-related Apoptosis-inducing Ligand Receptor-1 and -2," <i>The Journal of Biological Chemistry</i> , 276(5):3270-3278 (February 2, 2001)
	AS	Bergsland, et al., "Shedding Old Paradigms: Developing Viruses to Treat Cancer," <i>Journal of Clinical Oncology</i> , 20(9):2220-2222 (May 1, 2002)
	AT	Bert, et al., "Generation of an Improved Luciferase Reporter Gene Plasmid That Employs a Novel Mechanism for High-Copy Replication," <i>Plasmid</i> , 44:173-182 (September 2000)

EXAMINER

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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AM	WO 95/19434	7/20/95	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 96/34969	11/7/96	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
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	AP	WO 97/04805	2/13/97	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 97/48277	12/24/97	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Black, et al., "Regulation of E2F: A Family of Transcription Factors Involved in Proliferation Control," <i>Gene</i> , 237:281-302 (1999)
	AS	Boon, et al., "Cancer Tumor Antigens," <i>Current Opinion in Immunology</i> , 9:681-683 (1997)
	AT	Bouvet, et al., "Suppression of the Immune Response to an Adenovirus Vector and Enhancement of Intratumoral Transgene Expression by Low-Dose Etoposide," <i>Gene Therapy</i> , 5:189-195 (1998)

EXAMINER

DATE CONSIDERED

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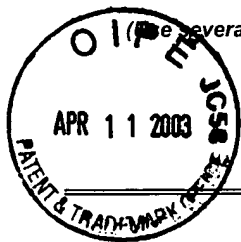
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## INFORMATION DISCLOSURE CITATION

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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
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	AM	WO 98/13508	4/2/98	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 98/27207	6/25/98	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AO	WO 98/28469	7/2/98	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 98/35028	8/13/98	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 98/39464	9/11/98	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Bristol, et al., "GM-CSF Containing Oncolytic Adenoviruses for the Treatment of Cancer," Abstract No. P2, presented at <i>The 10th Annual Meeting of the European Society for Gene Therapy</i> , Antibes, France, October 13-16, 2002
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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA						
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**FOREIGN PATENT DOCUMENTS**

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	AQ	WO 99/28469	6/10/99	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

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	AR	Bristol, et al., "In Vivo Anti-Tumor Activity of Oncolytic Adenoviruses that Express GM-CSF in Xenograft Tumor Models," <i>American Society for Gene Therapy, 5th Annual Meeting</i> , June 5-9, 2002; poster presented June 6, 2002
	AS	Bristol, et al., "In Vivo Anti-Tumor Activity of Oncolytic Adenoviruses that Express GM-CSF in Xenograft Tumor Models," <i>Molecular Therapy</i> , 5(5):abstract No. 311 (May 2002)
	AT	Bruder, et al., "Nuclear Factor EF-1A Binds to the Adenovirus E1A Core Enhancer Element and to Other Transcriptional Control Regions," <i>Molecular and Cellular Biology</i> , 9(11):5143-5153 (November 1989)

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	AS	Chang, et al., "Immunogenetic Therapy of Human Melanoma Utilizing Autologous Tumor Cells Transduced to Secrete Granulocyte-Macrophage Colony-Stimulating Factor," <i>Human Gene Therapy</i> , 11:839-850 (April 10, 2000)
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AD	Chiocca, E., "Oncolytic Viruses," <i>Nature</i> , 2:938-950 (December 2002)
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AI	Denome, et al., "Patterns of Polyadenylation Site Selection in Gene Constructs Containing Multiple Polyadenylation Signals," <i>Molecular and Cellular Biology</i> , 8(11):4829-4839 (November 1988)
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AG	Ennist, D., "Oncolytic Adenoviruses Containing GM-CSF for the Treatment of Cancer," abstract presented at the 4th International Conference, The Adjuvant Therapy of Malignant Melanoma, March 15-16, 2002
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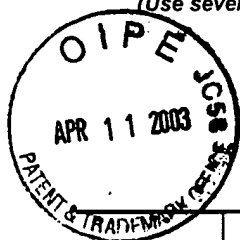


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AD	Gil, et al., "Position-Dependent Sequence Elements Downstream of AAUAAA Are Required for Efficient Rabbit $\alpha$ -Globin mRNA 3' End Formation," <i>Cell</i> , 49:399-406 (May 8, 1987)
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AK	Hallenbeck, P., "Oncolytic Adenoviruses Dependent Upon Two Prevalent Alterations in Human Cancer; Disregulation of the Rb-Pathway and Telomerase," oral presentation presented at the <i>3rd International Symposium on Genetic Anticancer Agents</i> , Amsterdam, The Netherlands, March 1-2, 2002
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AB	Hearing, et al., "The Adenovirus Type 5 E1A Transcriptional Control Region Contains a Duplicated Enhancer Element," <i>Cell</i> , 33:695-703 (1983)
AC	Heise, et al., "Efficacy of a Replication-Competent Adenovirus (ONYX-015) Following Intratumoral Injection: Intratumoral Spread and Distribution Effects," <i>Cancer Gene Therapy</i> , 6(6):499-504 (1999)
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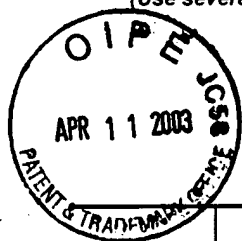
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AH	Johnson, et al., "Autoregulatory Control of E2F1 Expression in Response to Positive and Negative Regulators of Cell Cycle Progression," <i>Genes and Development</i> , 8:1514-1525 (1994)
AI	Johnson, et al., "Cytosine Deaminase-armed Selectively Replicating Adenovirus for the Treatment of Cancer," <i>Proceedings of the American Association for Cancer Research</i> , 43:656, abstract No. 3257 (March 2002)
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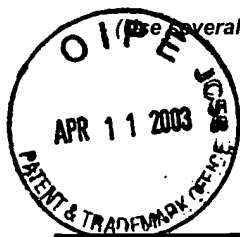
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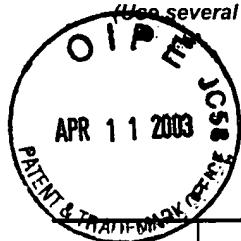
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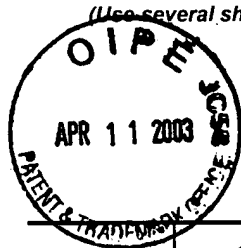
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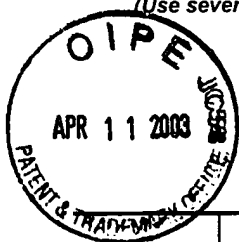
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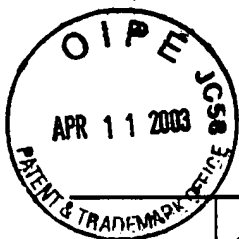
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